REMARKS

The foregoing amendments and the following remarks are submitted in response to the communication dated June 11, 2007.

Status of the Claims

Claims 1-21 were pending in the present application. By virtue of this response, claims 1-11, 20, and 21, which are withdrawn from consideration, have been canceled without prejudice. Each of claims 12, 13, 14, 15, 16, 17, 18, and 19 have been amended. Accordingly, claims 12-19 are currently under consideration. Support for the claim amendments can be found generally throughout the specification. In particular, support for the term "active fragment" can be found in the specification, including at paragraphs [020], [093], [107], [112], [113], and [114]. Support for the language "analog thereof having mutations or alterations in the microcin amino acid sequence" is found in the specification, including in paragraph [061].

With respect to all amendments and canceled claims, Applicant has not dedicated or abandoned any unclaimed subject matter and, moreover, has not acquiesced to any rejections and/or objections made by the Patent Office. Applicant reserves the right to pursue prosecution of any presently excluded claim embodiments in future continuation and/or divisional applications.

Claim Objections

The Examiner objects to claims 12, 13, 15, 17, and 18 for containing subject matter that is drawn to a non-elected invention, each of claims 12, 13, 15, 17 and 18 reciting reference to non-elected claim 1. Applicants have above amended claims 12, 13, 15, 17, and 18 for clarity and to include all of the limitations of claim 1.

Claim Rejections – 35 USC § 112

The Examiner rejects claims 14, 16, and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, the Examiner asserting that the claims contain subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner remarks that, while the claims are drawn to a method comprising administering an apoptogenic-bacteriocin comprising the amino acid sequence of SEQ ID NO:2 or an active portion or analog thereof, the specification discloses SEQ ID NO:2 for the processed, active microcin E492, and does not disclose any other active portions or analogs of SEQ ID NO:2 as broadly encompassed in the claims. The Examiner further states that to provide adequate written description and evidence of a claimed genus, the specification must provide sufficient distinguishing and identifying characteristics of the genus. Applicants respectfully disagree. The specification and the claims set out and describe specific and particular characteristics and capabilities of the apoptogenic-bacteriocin, particularly E492, suitable for and of use in the claimed methods. These provide tests for determining the capability and suitability of an active fragment or analog of microcin E492 or of SEQ ID NO:2 in the claimed methods. It is well within the capability and knowledge of the skilled artisan to make and test any such active fragments or analogs for use in the claimed methods and it is therefore unnecessary to further describe or detail fragments or analogs of the genus. The skilled artisan can readily do so, particularly given the teachings of the specification, his/her knowledge, and specific distinguishing and identifying characteristics of the genus as set out in the specification and in the claims. Applicants submit that claims 14, 16 and 19, particularly as above set out and amended, are fully and appropriately described by the instant disclosure.

The Examiner has further rejected claims 17-19 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement, containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most clearly connected, to make and/or use the invention. With regard to Claims 17-19, the Examiner takes the position that the specification does not provide examples or guidance for the prevention of cancer in a mammal. Applicants respectfully disagree and submit that the Specification provides sufficient examples and guidance. Applicants have above amended the claims, without prejudice, to be more particularly directed to treatment of cancer

and submit that this rejection is now made moot.

In addition, the Examiner has rejected Claims 12-16 and 19 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of apoptosis of tumor cell or cancer cells in a mammal, the treatment of cancer in a mammal, and reducing cancer growth in a mammal, comprising administering to said mammal an effective amount of the apoptogenic-bacteriocin of claim 1 or comprising the amino acid sequence of SEQ ID NO: 2, does not reasonably provide enablement for a method for apoptosis of cells undergoing aberrant growth in a mammal and a method for reducing any eukaryotic cell growth or blocking eukaryotic growth, comprising administering the apoptogenic-bacteriocin of claim 1 or SEQ ID NO: 2. The Examiner further asserts that the specification does not reasonably provide enablement for a method for apoptosis of tumor cells or cancer cells, reducing eukaryotic growth, or treating cancer in a mammal comprising administering any active portions or analogs of an apoptogenic-bacteriocin comprising SEQ ID NO: 2. Applicants respectfully disagree. Applicants point out that the claims as amended above, without prejudice, are more particularly directed to apoptosis of tumor or cancer cells. Applicants further assert that the specification, particularly in view of the significant skill of the skilled artisan, fully enables the making, testing and use of the claimed active fragments and analogs of microcin E492 and of SEQ ID NO: 2. The specification and the claims set out and describe specific and particular characteristics and capabilities of the apoptogenic-bacteriocin, particularly E492 and/or SEQ ID NO: 2 and active fragments or analogs thereof, suitable for and of use in the claimed methods. These provide tests for determining the capability and suitability of an active fragment or analog of microcin E492 or of SEQ ID NO: 2 in the claimed methods. It is well within the capability and knowledge of the skilled artisan to make and test any such active fragments or analogs for use in the claimed methods. Thus, Applicants argue: the state of the art for monoclonal antibodies at the time of the invention was significant; the predictability is enhanced by the disclosure and identification of several exemplary antibodies, the amount of direction or guidance is appropriate, particularly

given the significant skill and knowledge of the skilled artisan at the time; the claims set out appropriate breadth by providing specific testable characteristics for the antibodies of use in the methods; and the quantity of experimentation, while significant, is not undue. Applicants submit that claims 12-16 and 19, particularly as above set out and amended, are fully enabled by the instant disclosure.

In view of the foregoing remarks and above amendments, Applicants submit that the Examiner's rejections under 35 U.S.C. 112, first paragraph, may properly be withdrawn.

The 35 USC §102 Rejections

Claims 12, 15, and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent 5,968,894 [Lingwood, filed 11/28/1995, issued 10/19/1999] and as evidenced by Farkas-Himsley II [PNAS (1995) 92:6996-7000]. Linwood teaches the administration of verotoxin 1 (VT1) to mammals for the treatment of cancer. Frakas-Himsley II evidences that VT1 is the active component of bacteriocin isolated from *E. coli* strain HSC_{10}. Applicants respectfully disagree. Anticipation is a question of fact, and to anticipate a claim a prior art reference must teach or suggest each and every limitation of the claim. Applicant respectfully submits that Lingwood as evidenced by Farkas-Himsley II does not teach or suggest all elements of Applicant's claims, as amended, and therefore does not anticipate the claims. The claims as above presented are particularly and specifically directed to methods using microcin E492 or active fragments thereof. Verotoxin 1 is absolutely distinct from microcin E492 and does not have a sequence corresponding to that of microcin E492 or of SEQ ID NO:2. Thus, Lingwood and VT1, including as evidenced by Farkas-Himsley II, does not anticipate the instant claims.

The Examiner has rejected claims 12, 13, 15, 17, and 18 under 35 U.S.C. 102(b) as being anticipated by Hill et al [Cancer Res (1991) 51:1359-1365], as evidenced by Farkas-Himsley et al I [Cell and Molecular Biology (1992) 38:643-651]. Hill et al teach a method of treating cancer

and reducing tumor growth comprising administering a bacteriocin, Partially Purified Bacteriocin (PPB), to mice injected with KHT sarcoma cells. Although the Examiner acknowledges that Hill et al does not specifically teach that PPB induced apoptosis, she asserts that, as evidenced by Frakas-Himsley et al I, PPB induces apoptosis and selectively kills malignant cells. Anticipation is a question of fact, and to anticipate a claim a prior art reference must teach or suggest each and every limitation of the claim. Applicant respectfully submits that Hill et al as evidenced by Farkas-Himsley et al I does not teach or suggest all elements of Applicant's claims, as amended, and therefore does not anticipate the claims. The claims as above presented are particularly and specifically directed to methods using microcin E492 or active fragments thereof. PPB is absolutely distinct from microcin E492 and SEQ ID NO: 2. Thus, Hill et al and PPB, including as evidenced by Farkas-Himsleyet al I, does not anticipate the instant claims.

In view of the foregoing amendments and remarks, Applicants submit that the Examiner's 102 rejections are obviated and should be withdrawn.

CONCLUSION

Applicants respectfully request entry of the foregoing amendments and remarks in the file history of the instant Application. The Claims as amended are believed to be in condition for allowance, and reconsideration and withdrawal of all of the outstanding rejections is therefore believed in order. Early and favorable action on the claims is earnestly solicited.

Respectfully submitted,
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